

User's Manual

ZEN / QMX 01 / QMX 02 Cushions for stretcher



ZEN



QMX 01



QMX 02



This appliance conforms with the Directive 93/42/CEE "Medical Devices"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH

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Thank you for choosing a Spencer product

1 GENERAL INFORMATION

1.1 AIM AND CONTENTS

The aim of this manual is to give the client all necessary information to attain adequate use of the appliance in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 CONSERVATION OF THE INSTRUCTION MANUAL

The instruction and maintenance manual must be kept with the product, inside the specially provided packaging and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 SYMBOLS USED

SYMBOL	MEANING
	General or specific warning
	See instructions for use
	Lot number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on 0039 0521 541111 - fax 0039 0521 541222 - e-mail: service@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the lot number (LOT) on the label.

2 WARNINGS

2.1 GENERAL WARNINGS

- Before carrying out any kind of operation on the appliance, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l., for any necessary clarifications. Regularly check the appliance.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and the safety, the appliance must be immediately removed from service.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with. In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself. Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Ensure that all necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

2.2 SPECIFIC WARNINGS

- The product must be used by trained personnel only.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- When the device is being used, the assistance of qualified staff must be guaranteed.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

The use of this device, if used as described in this manual, does not present any contra-indications or collateral effects.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

The Spencer stretcher cushions ZEN, QMX 01 and QMX 02 are used to give nuchal support and keep the correct head alignment while offering additional comfort and safely to the patient.

3.2 MAIN COMPONENTS

Zen

Cushion in closed cell elastic compound

QMX 01

Heat sealed PVC cushion

QMX 02

- Adjustable cushion with Spentex® cover
- Knob for micro adjustment
- Velcro® strip for fixing to patient board

3.3 MODELS

QM50000A Zen Ergonomic cushion

QM50001A QMX 01 Welded cushion

QM50002A QMX 02 Automatic cushion

3.4 TECHNICAL DATA

	ZEN	QMX 01	QMX 02
Dimensions (mm)	260 x 200	410 x 450	320 x 350
Weight (g)	370	420	950
Thickness (mm)	maximum 200	45	minimum 35 / maximum 75
Material	closed cell elastic compound	PVC	PVC / Spentex®

3.5 ENVIRONMENTAL CONDITIONS

Functioning temperature: from 0 to +40 °C

Storage temperature: from 0 to +40 °C

Relative humidity: from 5 to 95%

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of damage, bumps or falls during the transport itself. Keep the original packaging for use in case of any further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The appliance must be stored in a dry place free from humidity.

4.2 PREPARATION

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.

ZEN and QMX 01 do not require fixing. The device QMX 02 has to be positioned as described in paragraph 4.2.1 "Fixing QMX 02 to stretcher patient board".

4.2.1 Fixing QMX 02 to stretcher patient board

1. Fix the adjustment now to the right or the left side of the Spencer DNA patient board.
2. Insert the tapered screw (n° 3 fig. A) in the corresponding hole on the DNA patient board and position it with the flange of the micro adjuster (n° 2 fig. A) which will have the bushing (n° 4 fig. A) positioned inside it.
3. Fix the parts together using the nut (n° 5 fig. A) and tighten the parts together until the knob is firmly attached to the patient board.

ATTENTION

Do not over force the screw so as to avoid damage to the device.

A n° 4 and hex key and n° 10 Allen wrench are required for assembly.

4. Once the adjustment device has been fixed, fix the Velcro® (supplied) in the ideal position required. Once the Velcro® strips are firmly fixed to the patient board, fix the cushion.

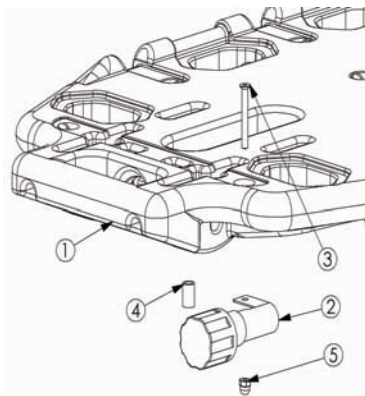


Fig. A

4.3 FUNCTIONING

ZEN



Optimum stability even when in hyperextension.



Maintains the head correctly aligned.



Minimises slipping and consequent friction with the cushion.



Allows correct positioning of the head.



Minimum thickness position.



Maximum thickness position.

4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
Excessive head movement	The cushion is not correctly positioned	Check that the patient's head is correctly positioned
Device damaged	Wear and tear Incorrect use	Remove the device immediately from service and contact the authorised service centre

5 MAINTENANCE AND CLEANING

5.1 CLEANING

Failure to carry out the correct cleaning procedure could increase the risk of cross infections. Avoid the use of any harsh chemical and or solvent. Wash using only mild detergents or soap and water. The use of high pressure water could damage the device. After washing a soft cloth should always be used to dry the device. While drying the device make sure that no residuals are left and that all detergents (which could cause material decay) have been correctly removed. This will help increase the life of the product.

5.2 MAINTENANCE

5.2.1 Precautionary Maintenance

The device does not require programmed servicing.

5.2.2 Special servicing

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device. The device, if used as indicated in the following instruction manual, has an average life span of 3 years. The life span can be expanded only following a general revision of the product that must be carried out by the manufacturer or by a centre authorised by the manufacturer.

6 ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

DR60550K Cushion cover for Zen, packet 50 pcs

6.2 SPARE PARTS

No spare parts are available for these products.

Warning

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.